K011718

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens

1. SUBMITTER INFORMATION

Bausch & Lomb Incorporated
1400 North Goodman Street
P.O. Box 0450
Rochester, NY 14692-0450

Contact Person: Debra Ketchum
Manager, Regulatory Affairs
Telephone No.: (716) 338-8638

2. DEVICE NAME

Classification Name: Soft (hydrophilic) contact lens

Proprietary Name: BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens

3. PREDICATE DEVICE

The BAUSCH & LOMB® SofLens™ One Day (hilafilcon A) Visibility Tinted Contact Lens has been selected as the predicate devices for the *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* produced with the monomer diluent.

4. DESCRIPTION OF DEVICE

The *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. It consists of a copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidinone, and is 70% water by weight when immersed in a sterile saline solution. This lens is tinted blue with either D&C Green #6 or Reactive Blue Dye 246 ((1,4-Bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone). The color additives conform with 21 CFR Part 74.3206 and 21 CFR Part 73.3106, respectively. The lens may also be supplied clear (no tint).

The physical / optical properties of the lens are:

Specific Gravity:	1.068
Refractive Index:	1.38
Light Transmittance:	C.I.E. Y value - at least 97%
Water Content:	70%
Oxygen Permeability (Dk):	33 $x10^{-11}$ [cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (Polarographic Method)

The *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon) Visibility Tinted Contact Lens* is a hemispherical shell of the following dimensions:

- Diameter: 13.5mm to 15.0mm
- Center Thickness: 0.05mm to 0.75mm
- Base Curve: 7.8mm to 9.5mm
- Powers (Spherical): +20.00D to -20.00D

Each *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* is supplied in a plastic blister container with a saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, diameter and expiration date.

5. INDICATIONS FOR USE

The *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Contact Lens. A summary of results from the preclinical tests is provided below.

Preclinical Testing:

A series of *in vitro* and *in vivo* preclinical toxicology testing was performed to assess the safety and effectiveness of the contact lens device. Testing was performed in accordance with FDA guideline titled Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994. All non-clinical laboratory studies were conducted in compliance with the GLP regulation.

The results of the preclinical testing on the *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* produced with the monomer diluent demonstrate that:

The physicochemical properties of the *BAUSCH & LOMB® SofLens™ one day (hilafilcon A) disposable Visibility Tinted Contact Lens* are equivalent to the currently marketed predicate device, BAUSCH & LOMB® SofLens™ One Day (hilafilcon A) Visibility Tinted Contact Lens.

The extracts of the lens material do not show any significant quantities of monomer components and toxicity testing results of lens material demonstrated no toxicity or irritation.

Substantial Equivalence

The *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* produced with the monomer diluent is similar to the currently marketed BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens, in that both fall into the same FDA material classification grouping (Group II) and both are manufactured by the same manufacturing process (cast molding). The *BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens* is different from the BAUSCH & LOMB® SofLens™ one day Disposable (hilafilcon A) Visibility Tinted Contact Lens in that it is manufactured using a monomer diluent, Glycerol. Glycerol is not included in the weight or mole percentages of the monomer mix, as it does not become part of the lens material. The difference between these two lenses will not have any negative effect on the safety and effectiveness of the device.

All product will be sold as sterile medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Bausch & Lomb, Inc.
c/o Ms. Debra Ketchum
Manager, Regulatory Affairs
1400 N. Goodman Street
P.O. Box 30450
Rochester, NY 14603-0450

Re: K011718
Trade Name: Bausch & Lomb® SofLens™ one day disposable (hilafilcon A)
Visibility Tinted Contact Lens
Regulation Number: 21 CFR 886.5925
Regulatory Class: Class II
Product Code: 86 MVN
Dated: June 1, 2001
Received: June 4, 2001

Dear Ms. Ketchum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14692-0450

Indications for Use Statement

510(k) Number (if known): K011718

Device Name: BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens

Indications for Use:

The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Claims:

1. The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens provides vision correction in powers ranging from +20.00D to -20.00D.

2. The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is for single-use disposable wear.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____

Daniel W. C. Brown, PH.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K011718